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In The

Supreme Court of the United States

October Term, 1998

FOOD AND DRUG ADMINISTRATION, ET AL.,

Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fourth Circuit

AMICUS CURIAE IN SUPPORT OF PETITIONERS' PETITION FOR A WRIT OF CERTIORARI

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25pp

TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

INTEREST OF AMICUS CURIAE[1]

Amicus Curiae, Action on Smoking and Health (ASH) is the oldest and largest anti-smoking organization in the country dedicated solely to the issues to tobacco and smoking. ASH is a national non-profit scientific and educational organization that for over 30 years has focused on the problems of tobacco, and protecting the rights of non-smokers not to have to breathe in other persons' tobacco smoke. ASH and its Executive Director, John F. Banzhaf III, have brought many legal actions related to smoking, including *Banzhaf v. FCC*, 405 F.2d 1082 (D.C. Cir. 1968) (upholding FCC ruling that televisions and radio stations must provide substantial free time for anti-smoking messages), *Capital Broadcasting Co. v. Mitchell*, 333 F. Supp. 582 (D.C. 1971) (upholding enforcement of the federal statute which prohibits cigarette advertising on any medium of electronic communication subject to jurisdiction of the Federal Communications Act), *National Association of Motor Bus Owners v. United States*, 370 F. Supp. 408 (D.D.C. 1974) (upholding ICC regulation restricting smoking on buses traveling in interstate commerce as a proper exercise of ICC jurisdiction and a reasonable exercise of ICC's rule-making authority), and *ASH v. CAB*, 699 F.2d 1209 (D.C. Cir. 1983) (requiring former Civil Aeronautics Board to

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[1] John F. Banzhaf III, Chief Counsel and Kathleen E. Scheg, Legislative Counsel authored the brief for ASH. No counsel for either party authored the brief in whole or in part and no one apart from ASH's donor members made a monetary contribution to the preparation or submission of this brief.

Consent to the filing of this brief has been granted by the parties. Their letters of consent are attached.

adopt reasonable regulations for non-smoking sections on airplanes, since expanded to a ban on smoking on almost all domestic flights).

ASH has a special interest in the instant case because over 20 years ago, in 1977, Action on Smoking and Health petitioned the FDA to regulate tobacco products as "drugs". In 1978, ASH again petitioned the FDA to regulate cigarettes, this time as "devices," under the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, 21 U.S.C. 301 et seq. These petitions led to the decision of the court in *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980) which in ASH's opinion has been misconstrued by the majority in the Fourth Circuit in the instant case.

Moreover, ASH's 32 years of knowledge and experience in addressing issues related to tobacco products puts it in a unique position to assist the Court in understanding the importance to the public of the Court granting a writ of certiorari in this case. Underlying the legal issues presented in this case is the source of the leading preventable cause of death, disease and disability in the Nation. There is no more important public health issue, and the authority of the FDA to regulate tobacco products will affect millions of people well into the next millennium.

SUMMARY OF ARGUMENT

Amicus Curiae, Action on Smoking and Health (ASH) urges the court to grant the Food and Drug Administration's (FDA) Petition for Writ of Certiorari. ASH supports the FDA Petition because the case is of utmost public importance, and because there is a conflict between this case from the Fourth Circuit and an earlier case from the United States Court of Appeals, District of

Columbia Circuit, namely *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

The instant case is of utmost public importance. Tobacco products, which the FDA seeks to regulate, are the leading preventable cause of death in the United States, killing over 400,000 people a year. The FDA regulation of tobacco products can also have a significant impact on the U.S. economy, which now incurs over $130 billion a year from medical and other costs caused by smoking-related illnesses.

The conflict between the Fourth Circuit and the District of Columbia Circuit is over the authority of the FDA to regulate tobacco products and the deference the courts should give to the agency's interpretation of its own statute, the Federal, Food, Drug and Cosmetic Act, (FDCA) ch. 675, 52 Stat. 1040, 21 U.S.C. 321 et seq. While the D.C. Circuit looked to the language of the statute, deferred to the agency's interpretation, and allowed for subsequent revision of that interpretation in light of new information, the Fourth Circuit has refused to defer to the FDA's interpretation of its own statute. Instead, it has relied on extrinsic evidence, including a convoluted and incomplete analysis of Congressional inaction.

I. MAJOR PUBLIC HEALTH AND ECONOMIC ISSUE

The question presented in this case, whether the FDA has authority to regulate tobacco products, is of critical importance to the public health and to the economy of this nation. As former U.S. Secretary of Health, Education and Welfare, Joseph Califano stated in testimony before the House Energy and Commerce Committee's Subcommittee on Health on May 17, 1994:

> Had we known what the tobacco companies knew and had we been privy to their research on the addictive nature of nicotine and their ability to manipulate the amount of nicotine in cigarettes, the 1979 Surgeon General's report would have found cigarettes addictive and we would have moved to regulate them. Unfortunately, the President of the United States, the Secretary of Health, Education, and Welfare, and the Surgeon General of the United States were all victims of the concealment and disinformation campaign of the tobacco companies.

A. Public Health Importance

This case is of immense public health importance because the use of tobacco products is the single leading cause of death in the United States.[2] Over 400,000 Americans die each year from tobacco diseases.[3] This is more than the combined deaths each year from AIDS, car accidents, alcohol, homicides, illegal drugs, suicides and fires.[4]

Moreover, smoking is predominately a "pediatric disease." A person who does not initiate tobacco use as a minor is unlikely to begin as an adult. Despite the fact that the sale of tobacco products to minors is illegal in all 50 states, over 80 percent of smokers begin smoking

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[2] Lynch, Barbara S., and Bonnie, Richard J., eds., Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths, Institute of Medicine, National Academy Press, Washington, D.C., 1994., p. 3. (Hereafter referred to as IOM.)

[3] "Cigarette Smoking – Attributable Mortality and Years of Potential Life Lost – United States, 1990," MMWR, CDC, DHHS, 42(33):645-649.

[4] IOM, op. cit., p. 3.

before age 18, and more than half become regular smokers while still a minor.[5] Currently, approximately 3 million American children smoke,[6] and each year another 1 million minors become regular smokers.[7] Approximately one third of these children will eventually die as a result of their tobacco use.[8] This is truly a national tragedy.

B. Important Economic Ramifications

These deaths caused by tobacco use often are preceded by lengthy periods of illness, imposing an extraordinary burden on the United States economy in health care costs and lost productivity,[9] and thus making the

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[5] U.S. Surgeon General, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General*, U.S. Government Printing Office, Washington, D.C., 1994, p. 65. (hereafter referred to as SGR 1994.)

[6] 1994 SGR, op. cit. p. 5.

[7] IOM Report, op. cit., p. 8.

[8] Memorandum from Michael P. Ericksen (CDC) to Catherine Lorraine (FDA) August 7, 1995, and CDC Fact Sheet; citing Pierce, J.R., M.C. Fiore, T.E. Novotny, E.J. Hatziandreu, and R.M. Davis, Trends in Cigarette Smoking in the United States: Projections to the Year 2000, JAMA 261:61-65, 1989; Unpublished data from the 1986 National Mortality Followback Survey, CDC, OSH; Peto, R., A.D. Lopez, J. Boreham, M. Thun, and C. Health, "Mortality from Smoking in Developed Countries, 1950-2000: Indirect Estimates from National Vital Statistics," Oxford University Press, Oxford, 1994.

[9] See generally U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Office on Smoking and Health, Reducing the Health Consequences of Tobacco: 25 years of Progress, A Report of the Surgeon General (Atlanta, Georgia: U.S. Government Printing Office, 1989); U.S.

case of great public importance also to the economy of the Nation. According to a recent analysis conducted by the United States Department of the Treasury, smoking will cost the nation $130 billion a year, of which $45 million is attributable to medical costs due to smoking related diseases.[10]

These twin tragedies of devastating personal loss due to death and disease caused by tobacco use, and the immense financial cost for the U.S. economy, make regulation of tobacco products by the FDA an issue of extreme public importance. It is one of the reasons why ASH supports the FDA petition for a writ of certiorari in this case.

C. Demonstration of Public Importance

The immense public importance is also why national health experts and leading public health organizations have all strongly supported the FDA regulation of tobacco products. Most significantly, the Advisory Committee on Tobacco Policy and Public Health, co-chaired by former U.S. Surgeon General C. Everett Koop, M.D., Sc.D, and former FDA Commissioner David A. Kessler, M.D., and composed of the leaders in tobacco control

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Department of Health and Human Services, Centers for Disease Control and Prevention, Office on Smoking and Health, Preventing Tobacco Use Among Young People, A Report of the Surgeon General (Atlanta, Georgia: U.S. Government Printing Office, 1994.)

[10] 144 Cong. Rec. S6007-2 (daily ed. June 10, 1998) (statement of Senator Kennedy) referring to "the Economic Costs of Smoking in the United States and the Benefits of Comprehensive Tobacco Legislation", a report of the Department of the Treasury, March 1998.

from the major public health groups,[11] concluded unanimously that the FDA should have unrestricted authority to regulate tobacco products. After noting that "nicotine in cigarettes and smokeless tobacco has the same pharmacological effects as other drugs that FDA has traditionally regulated."[12] the Advisory Committee recommended:

- FDA should continue to have authority to regulate all areas of nicotine, as well as other constituents and ingredients, and that authority should be made completely explicit.
- FDA should continue to have the authority to phase out nicotine and remove ingredients that contribute to the initiation of smoking and dependence on cigarettes and other tobacco products (including smokeless tobacco, pipes, cigars, and roll-your-own tobacco), and that authority should be made completely explicit.

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[11] These include: Action on Smoking and Health, Advocacy Institute, Amer. Acad. of Family Physicians, Amer. Academy of Pediatrics, Amer. Cancer Society, Amer. Coll. of Chest Physicians, Amer. Coll. of Preventive Medicine, Amer. Heart Association, Amer. Lung Association, Amer. Medical Association, Amer. Medical Women's Assn, Amer. Public Health Assn, Amers. for Nonsmokers' Rights, Assoc. State/Terr. Health Officials, Natl Center for Tobacco-Free Kids, National Medical Association, Onyx Group, Partnership for Prevention, Science and Public Policy Institute, Smokeless States National Program, Stop Teenage Addiction to Tobacco, Tobacco Products Liability Project.

[12] Final Report of the Advisory Committee on Tobacco Policy and Public Health, co-chair, C. Everett Koop, M.D., Sc.D. and David A. Kessler, M.D., July 1997, pp. 3-4.

- There should be *no* limitations on or special exceptions to FDA authority to regulate nicotine, other constituents, and ingredients of tobacco products and such a no-limitations policy should be made completely explicit.
- The FDA should continue to have authority to regulate further nicotine, other constituents, and ingredients as the evidence suggests. The best science, information, and health policy (and not an arbitrary deadline) should drive FDA regulatory timing and that authority should be made completely explicit.
- The FDA should have the authority to test nicotine levels by brand, based on the best science and that authority should be made completely explicit.
- Regulation of non-tobacco nicotine delivery devices (e.g., nicotine patches, nicotine gum, nicotine inhalers, etc.) should be done in a manner that does not make the development and sale of less hazardous systems difficult and that encourages maximum overall reduction in disease.[13]

Major medical and public health organizations have also individually strongly supported the FDA regulation of tobacco products. These include, for example:

1. The American Medical Association (AMA)

Official AMA policy states that: "[T]he AMA supports the regulation of tobacco products by the FDA."[14] Moreover, the AMA also recently reiterated that policy in

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[13] *Ibid.*

[14] AMA Policy Compendium, H-490.962 (Res. 243, A-89; Reaffirmed in lieu of Res. 232, I-94, Sub, Res, 406, I-95, Reaffirmation I-96).

its *Journal of the American Medical Association* in which after stating that: "the consequences of tobacco to the public health have been, and will continue to be, staggering, and the importance of bringing this hazard under control is correspondingly great",[15] the AMA recommended, inter alia, that "[t]obacco itself should be considered a drug delivery vehicle and placed under the oversight of the Food and Drug Administration, with appropriate regulation as for other life-threatening drugs.[16]

2. American Cancer Society (ACS)

> The American Cancer Society . . . applaud(s) Dr. David Kessler and the Clinton Administration for their courageous leadership in dealing with one of the biggest public health crises of our time. . . . We support this rule without reservation. In what will prove to be one of the most important public health measures of our time, the Food and Drug Administration has just released regulations asserting jurisdiction over tobacco for the first time.[17]

3. American Lung Association (ALA)

> . . . . We commend the FDA for assuming jurisdiction over tobacco products through its rule to protect children.

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[15] Lundberg, Editor, *The Brown and Williamson Documents: Where Do We Go From Here*, 274 JAMA 256 (1995).

[16] *Ibid.* p. 258 citing Lundberg GD, Tobacco for consenting adults in private only, 255 JAMA 1051-1053(1986).

[17] Statement by George Dessart, Chairman of the American Cancer Society, on release of the final FDA regulations on tobacco.

. . . . It is ludicrous that nicotine gum and nicotine replacement patches, which are designed to break the chain of tobacco addiction, are strictly regulated by the FDA, while cigarettes and smokeless tobacco products, which disable and kill hundreds of thousands of people each year, get off the regulatory hook.

Today's action and request of the FDA are a continuation of the efforts that were started in 1988 when the American Lung Association, the American Heart Association and the American Cancer Society and a number of other organizations filed the first in a number of petitions with the FDA, asking the FDA to declare jurisdiction over tobacco products and to apply comparable regulatory standards to tobacco products as is applied to drugs and devices.[18]

4. American Public Health Association (APHA)

. . . The American Public Health Association (APHA) applauds the Administration's swift action that allows the FDA to regulate the sale and advertising of tobacco products to minors.

. . . APHA agrees with Dr. Kessler that nicotine is an addictive drug, and adds that tobacco use caused by addiction to nicotine causes 500,000 preventable deaths in the United States each year.[19]

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[18] Press Briefing, Statement of John R. Garrison, Managing Director, American Lung Association, "Petition to the Food and Drug Administration", Washington, D.C., January 15, 1998.

[19] American Public Health Association, Press Release, "Regulating Adolescent's Access To Tobacco Will Reduce the Number of Children Who Begin Smoking Each Day," August 23, 1996.

5. Association of State and Territorial Health Officials (ASTHO)

. . . . The Association of State and Territorial Health Officials (ASHTO), representing the chief public health officials in each state and U.S. territory, stated today its enthusiastic support for the Food and Drug Administration's regulations monitoring the sale and promotion of tobacco products to protect children and adolescents.[20]

6. American College of Physicians

. . . . The American College of Physicians, the nation's largest medical specialty society representing 89,000 internists, fully supports the action today by the President and the Food and Drug Administration to regulate tobacco as a drug delivery device. . . . Tobacco addiction most often begins in children and adolescents, and statistics show that continued tobacco use is the cause of more than 400,000 deaths each year.

Tobacco-related diseases are the single most preventable cause of death, disease and disability in the United States. The nation's internists – specialists in adult medicine and the care of cancer, respiratory, and a cardiac illness – know that forceful action is essential to eliminate this epidemic.[21]

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[20] Association of State and Territorial Health Officials, Press Release, "State Health Officials Welcome New Tobacco Regulations", Washington, D.C., August 23, 1996.

[21] American College of Physicians, Press Release, "American College of Physicians: Regulate Tobacco" Philadelphia, PA, August 23, 1996.

II. CONFLICT OF JURISDICTIONS

ASH urges the Court to grant certiorari in this case because, in addition to its involving a matter of supreme public health importance, the instant case, *Brown and Williamson Tobacco Corp. v. Food and Drug Administration*, 153 F.3d 155 (4th Cir. 1998) from the United States Court of Appeals for the Fourth Circuit, conflicts with *Action on Smoking and Health v. Harris*, 655 F.2d 236 (1980) deciding by the United States Court of Appeals, District of Columbia Circuit. The Circuits conflict on the authority of the FDA to regulate tobacco products and the deference that the courts should give to an agency's interpretation of its own statute.

In *Action on Smoking and Health*, the U.S. Court of Appeals for the D.C. Circuit, defers to the FDA's interpretation of its statute, the FDCA, but in the instant case *Brown and Williamson Tobacco Corp. v. Food and Drug Administration*, the Fourth Circuit substitutes a de novo interpretation of the statute.

In discussing the standard of review of the FDA's action, the U.S. Court of Appeals, District of Columbia Circuit, concluded that a "deferential approach is mandated", stating in relevant part:

> . . . . ASH would have this court substitute its judgment for that of the commissioner, approaching the question of statutory interpretation de novo. We do not believe that such an approach is warranted in this case.
>
> On the contrary, the construction and application of a statute by those charged with its administration is entitled to substantial deference. . . . [citations omitted]. This court has noted two basic rationales justifying a deferential regard for administrative interpretation of

> statutes: administrative expertise and congressional acquiescence in the administrative interpretation. . . . [citations omitted] We believe that the latter basis is relevant to the consideration of the administrative interpretation at issue here and agree with the district court. . . . [citations omitted].

By contrast, in the instant case in the U.S. Court of Appeals for the Fourth Circuit, the majority refuses to defer to the agency's interpretation of its own FDCA, and instead enters into a convoluted analysis of Congressional intent despite "as much as conceding that tobacco products fit the FDA's 'literal' definition of a drug." *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d at 177.

The majority concedes that "[a] mechanical reading of only the definitions provisions may appear to support the government's position that tobacco products fit within the Act's definitions of drugs and devices. *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d at 163. Moreover, the majority had previously acknowledged that:

> The FDA correctly contends that the language of the statute must be the starting point of our analysis. We agree that the first step of statutory construction is determining the plain meaning of the statutory language when the language is unambiguous and "the statutory scheme is coherent and consistent." *Robinson v. Shell Oil*, 65 U.S.L.W. 4103, 4104 (U.S. Feb. 18, 1997) (No. 95-1376) (quoting *Ron Pair Enter.*, 489 U.S. at 249, 109 S.Ct. 1026).

Nonetheless, the majority then refuses to defer to the FDA's determination that the tobacco products fit within the statutory language of the FDCA and instead embarks on an analysis of Congressional intent.

Even here, after conceding that the Court "do[es] not dispute in this case that Congress has charged the FDA with protecting the public health and that tobacco products present serious health risks for the public", *id.* at 167, the Court still refuses to defer to agency discretion. Instead the majority looks to "extrinsic evidence" to reach its conclusion "that Congress did not intend to delegate jurisdiction over tobacco products to the FDA." *Id.* at 176.

III. CONGRESSIONAL INTENT

Although ASH contends that the FDA's jurisdiction to regulate tobacco products can be upheld based on deference to the FDA's interpretation of its own statute, and there is no need to look to extrinsic information as the majority of the Fourth Circuit did, a review of Congressional intent actually supports FDA regulation of tobacco products rather than undermines it as the majority in the Fourth Circuit concluded.

A. Historical Inaction By FDA

The majority in the Fourth Circuit erroneously rely on historical inaction by the FDA and in particular the agency's refusal in *ASH v. Harris*, 656 F.2d 236 (1980), to assert its jurisdiction over tobacco products, as a basis for finding that Congress didn't intend to give the FDA authority over tobacco products. Contrary to the suggestion that *ASH v. Harris* supports the Fourth Circuit opinion, that case actually provides the foundation for the FDA's decision to regulate tobacco products now that an abundance of new information has come to light in recent years through the release of tens of thousands of previously secret tobacco industry documents, which clearly

show that tobacco products meet the statutory definition of "drugs" or "devices", 21 U.S.C. 321(g)(1)(C) and (h)(3), and that the tobacco industry has known this for years and withheld the information from the public.

For example, in one document which recently became public, Addison Yeaman, general counsel to Brown and Williamson ("B&W"), declared in a memorandum to colleagues, "Moreover, nicotine is addictive. We are, then, in the business of selling nicotine, an addictive drug effective in the release of stress mechanisms."[22]

In another recently disclosed document, Claude E. Teague, Jr., an assistant director of research at R.J. Reynolds who was later promoted to an executive position stated:

> In a sense, the tobacco industry may be thought of as being a *specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products*, uniquely, contain and deliver nicotine, a *potent drug* with a variety of physiological effects . . . Thus a tobacco product is, in essence, *a vehicle for delivery of nicotine*, designed to deliver the nicotine in a generally acceptable and attractive form. Our industry is then based upon design, manufacture and sale of attractive dosage forms of nicotine. . . . (emphasis added)[23]

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[22] Addison Yeaman, "Implications of Battelle Hippo I & II and the Griffith Filter," 1963, quoted in John Slade, et al., "Nicotine and Addiction: The Brown and Williamson Documents," J.Am.Med.Ass'n, Vol. 274, No. 3, pp. 225-33, July 19, 1995 (emphasis added).

[23] Claude E. Teague, Jr., "The Nature of the Tobacco Business and the Crucial Role of Nicotine Therein, Research Planning Memorandum," R.J. Reynolds, April 14, 1972 (Minn. trial exh. 12408).

These and over 40,000 other previously secret tobacco industry documents provided substantial new facts on which the FDA could reevaluate its decision to regulate tobacco products. As Judge Hall said in his dissent:

> It is a familiar canon of administrative law that an agency can change its view of what action is possible or necessary, particularly when new facts come to light. See *Rust v. Sullivan*, 500 U.S. 173, 186-87 (1991) ("An agency . . . must be given latitude to adapt its rules and policies to the demands of changing circumstances") (citations and internal quotation marks omitted). Even when upholding the FDA's earlier denial of its own power to regulate tobacco, the court (U.S. Court of Appeals, District of Columbia Circuit) added the following caveat:
>
> > Nothing in this opinion should suggest that the [FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations. . . . The very structure of the [FDAC] which the FDA must administer, moreover, calls for case-by-case analysis. Should an agency depart from its prior interpretations, however, it must provide a reasoned explanation for its action. . . . [citations omitted]. ASH, 655 F.2d at 242 n.10

B. Congressional Action

Despite acknowledging "the general reluctance of courts to reply on congressional inaction as a basis for statutory interpretation, *See Brecht v. Abrahamson*, 507 U.S. 619, 632 (1993) (noting that '[a]s a general matter, "we are reluctant to draw inferences from Congress's failure to

act" ') (quoting *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 306 (1988))", *Brown and Williamson Tobacco Corp. v. Food and Drug Administration*, 153 F.3d at 170, the majority of the Fourth Circuit then interprets Congress' failure to enact legislation specifically granting the FDA jurisdiction over tobacco products as legislative acquiescence in FDA's earlier decision not to regulate tobacco. Yet certainly more significant than congressional inaction during the years when the tobacco companies concealed the relevant information about the addictive properties of nicotine from Congress and the public at large, thereby providing Congress with no basis for action, is the Congressional inaction in light of the FDA regulations on tobacco currently under review.

The FDA regulations which are the subject of this case were published in the Federal Register as a proposed rule on August 11, 1995 (60 Fed. Reg. 41,314) and as final regulations on August 28, 1996 (61 Fed. Reg. 44,619) and received extensive public coverage. In addition, FDA Commissioner David A. Kessler testified several times before Congressional committees on this issue. In his widely-televised remarks, he told the members that newly-discovered evidence about the addictive nature of nicotine, and cigarette maker's knowledge of this property and their efforts to manipulate it, would force the FDA to regulate nicotine in cigarettes – as it has long regulated nicotine in other forms (e.g., in patches, chewing gum, and inhalants) if Congress declined to amend the statute. In the almost four years since this public announcement, there has been no serious Congressional attempt to remove FDA's authority to regulate tobacco products, an indication surely of legislative acquiescence not only in FDA's authority generally to regulate tobacco

products, but specifically an acceptance of the specific FDA regulations for tobacco products now before the Court.

Additionally, it is instructive to note that Congress has excluded tobacco products from other federal laws and clearly could have done so with the Food, Drug and Cosmetic Act. Federal laws which specifically excluded tobacco products, include:

1. The Federal Hazardous Substances Act

   Under the heading "definitions", the Federal Hazardous Substance Act specifies that the term "hazardous substance" does not include "tobacco and tobacco products" Sec. 2(f)(2). P.L. 86-613, signed July 12, 1960.

2. Fair Packaging And Labeling Act

   Under the heading "definitions", the Fair Packaging and Labeling Act specifies that the term "consumer commodity" does not include "any . . . tobacco or tobacco product" Sec. 10(a)(1), P.L. 89-755, signed November 3, 1966.

3. Consumer Product Safety Act

   Under the heading "definitions", the Consumer Product Safety Act specifies that the term "consumer product" does not include "tobacco and tobacco products." Sec. 3(a)(1)(B), P.L. 92-573, signed October 27, 1972.

4. Toxic Substances Control Act

   Under the heading "definitions", the Toxic Substance Control Act specifies that the term "chemical substances" does not include "tobacco or any tobacco product." Sec. 3(2)(B)(iii), P.L. 94-469, signed October 11, 1976.

Most significantly, as recently as 1994, Congress explicitly excluded tobacco from the "dietary supplements" exemption from the definitions of a "drug" in the FDCA itself.[24]

Clearly, Congress could have excluded tobacco entirely from the coverage of the FDCA at the time. It did not. In fact, it can be argued that by excluding tobacco from the "dietary supplements" definition, Congress was expressing its intent to retain FDA jurisdiction over tobacco as a "drug".

As with the "dietary supplements" provision and the other laws in which Congress uniquely excluded tobacco products, it could have done so with the Food, Drug & Cosmetic Act. It did not. Moreover, in the years since FDA announced its intention to begin regulating tobacco products in light of the new information that it had received, Congress has made no attempt to preclude FDA regulation of tobacco. In effect, Congress has acquiesced in the FDA regulation of tobacco products. Congressional inaction supports FDA jurisdiction over tobacco products and the upholding of the current regulations rather than undermining it as the majority in the Fourth Circuit contends.

IV. CONCLUSION

Amicus Curiae, Action on Smoking and Health, supports the FDA's Petition for Writ of Certiorari. ASH urges the Court to grant the Writ. In addition to the arguments made by the FDA, ASH urges the Court to grant the Writ because of the utmost public importance of the case. Inasmuch as the tobacco products, which the FDA seeks

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[24] Pub L. No. 103-407, sec. 2(a), 108 Stat. 4325, 4327 (codified at 21 U.S.C. sec. 321(ff)(1)).

to regulate, are the leading preventable cause of death in the United States, killing over 400,000 people a year, a decision in this case will have major public health ramifications well into the next millennium. It will also have a major impact on the U.S. economy due to the billions of dollars of health care and other costs related to smoking.

Additionally, ASH urges the Court to hear this case because the decision of the Fourth Circuit in the instant case conflicts with the United States Court of Appeals, District of Columbia Circuit, regarding the deference that courts should give to the FDA's interpretation of its own FDCA and, in particular, its authority to regulate tobacco products. Further, in refusing to defer to agency discretion, the Fourth Circuit presents an incomplete and convoluted analysis of Congressional intent, which, if left to stand, could seriously undermine the FDA's ability to regulate other "drugs" and "devices" which put the public at serious risk of death and disease.

Respectfully submitted,

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